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Certified/Return Receipt Requested

WARNING LETTER

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

August 30, 2000

Mr. Chris J. Szczucinski
Owner and President
Great Plains Seafood, Inc.
6360 Carter
Merriam, Kansas 66203-3600

Ref. KAN 2000- 024

Dear Mr. Szczucinski:

We inspected your firm, located at the above address on July 17-20, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh tuna, mahi-mahi, shellfish and cooked crabmeat to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

Some of the deviations observed during the inspection were:

You do not have a HACCP plan to control growth of pathogens from post process contamination for cooked crabmeat distributed by your firm. Your failure to have a written HACCP plan for processing of seafood products was addressed in a letter to you dated March 5, 1998. To comply with 21 CFR 123.6(b), you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur.

Your critical limit of 45degrees Fahrenheit for receipt of fresh tuna, mahi mahi, and live invertebrates (oysters, mussels, and clams) is not adequate to control histamine formation, and/or pathogen contamination. Compliance with 21 CFR 123.6(c)(3) requires listing of critical limits that must be met at each critical control point.

You did not take corrective action to control histamine formation when your receipt of fresh tuna and mahi mahi deviated from your critical limit of 45 degrees Fahrenheit or less internal temperature. To meet requirements of 21 CFR 123.7(a), appropriate corrective action must be taken when a deviation from a critical limit occurs.

You failed to maintain monitoring observations for fresh tuna and mahi mahi that sufficient ice or other cooling medium was present at time of receipt to adequately control histamine formation. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123 (6)(b).

You did not monitor sanitation control procedures such as: prevention of cross contamination from insanitary objects contacting food products and food contact surfaces; condition and cleanliness of food contact surfaces; protection of food, and food contact surfaces from chemical, physical and biological contaminants.

Examples of inadequate sanitation monitoring include, but are not limited to: an employee's cotton gloved hand inside a container of shucked oysters and cooked crab meat; processing residue build-up on processing tables, knives and scale platforms; hose overspray containing sanitizing and foaming agents splashing from floors onto processing equipment, and into containers of seafood products.

Requirements for sanitation monitoring, and examples of your firm's failure to conduct such monitoring, including some similar to those noted above were addressed in a letter to you dated March 5, 1998. In order to comply with 21 CFR 123.11(b), you must monitor sanitation conditions and practices appropriate to your plant and food processing operations to ensure at a minimum that requirements of 21 CFR 110 are met.

We may take further action if you do not promptly correct these violations. Actions that may be taken include seizure of your products and/or injunction to prevent operations of your firm.

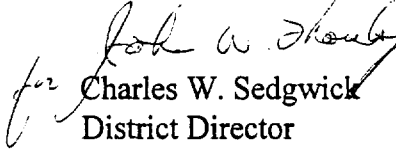
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter does not list all the deviations observed, or that otherwise may be occurring at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

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Please send your reply to the Food and Drug Administration, Attention: Noel G. Ferguson, Compliance Officer, P.O. Box 15905, Lenexa, Kansas 66285-5905. If you have questions regarding any issue in this letter, please contact Compliance Officer Ferguson at (913) 752-2102.

Sincerely,


for Charles W. Sedgwick
District Director
Kansas City District